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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,722	02/05/2002	Victor C.W. Tsang	6395-62261	2650

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,722	TSANG ET AL.	
	Examin r	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendments filed on 6/30/03 (paper # 7) and 7/31/03 (paper # 9) are acknowledged. Claims 8-20 are canceled. Claims 4, 5, 23 and 25 have been amended. New claims 26 and 27 have been added. Claims 1-7 and 21-27 are pending in the application.

Objections and Rejections withdrawn

2. In view of amendment to the claim 25, the objection as being improper dependent form is withdrawn.

3. In view of amendment to the claims, the rejection under 35 U.S.C. 112, second paragraph, is withdrawn.

4. In view of submission of Declaration under 37C.F.R 1.132, the rejection of claims 1-7and 21-25 under 35 U.S.C. 102(a) as being anticipated by Wilkins et al is withdrawn.

5. In view of submission of Declaration under 37C.F.R 1.131, the rejection under 35 U.S.C. 103(a) as being unpatentable over Ko and Ng 1998(Journal of Helminthology 72, 147-154) for claims 1-7 and 21-25 is withdrawn.

Rejection maintained

6. The rejection of claims 1 and 21-25 under 35 U.S.C. 102(b) as being anticipated by McManus Donald 1995 (Papua New Guinea Medical Journal, Vol.38, No.4, 287-294) is maintained as set forth in the previous Office action.

McManus Donald, 1995, discloses excretory or secretory molecules (ES) in serum or CSF. Further the prior art discloses that these antigens were identified by an ELISA assay and thus read on claims 21-24 because in an ELISA assay antigen binds to the solid surface I.e., ELISA plate. Labeling peptide in an immuno assay is well known in the art (see abstract and page 289). Claim 25 is being viewed as a composition, claim 1. The prior art anticipated the claimed invention.

Applicants' arguments filed on 6/30/3 (paper # 7) have been fully considered but they are not deemed to be persuasive.

Applicant asserts that McManus does not disclose all the elements of the claims as required by the statute and Mc Manus discloses larval antigens but not adult ES T.solium antigens.

It is the position of the examiner that McManus Donald, 1995, discloses antigens, excretory or secretory (ES) molecules (see page 289, left column, last paragraph through right column, first paragraph) from serum or CSF that are captured (i.e., isolated) by an ELISA assay using monoclonal and polyclonal antibodies. Since parasite products from human serum samples confirms the presence of living parasites it reads on the claimed composition because adult ES polypeptide as claimed has no structural characteristics to differentiate between larval and adult. In the absence of evidence to the contrary the disclosed prior art excretory and secretory molecule read on the claimed composition.

New Rejection based on the amendment

Claim Rejections - 35 USC 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7, 21-22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Varma et al 1986 (Indian Journal of Animal Sciences 56 (6): 621-627).

Claims are directed to a composition or a kit comprising an isolated adult T.solium excretory secretory polypeptide, said composition is immobilized to a solid phase.

Varma et al disclose a composition comprising adult tapeworm crude antigens (see page 621, under Antigen) for identifying the adult antibodies in sera collected from human patients suffering from T.solium infection. Adult worms were homogenized and used as an antigen in an ELISA plate (i.e., solid phase) in an agglutination assay. Homogenized adult crude antigenic preparation of Varma et al inherently comprise a mixture of ES polypeptides as adult worms contain antigens that were going to be excreted and secreted at the time antigen preparation. Characteristics such as molecular weight is considered to be an inherent property of the tapeworm antigens. Kit is considered as a composition comprising adult secretory antigen in a solid phase. Therefore, the prior art anticipated a kit comprising composition on a solid phase. Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed composition and the prior art composition. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11 Claims 1-7 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over

McManus Donald 1995 (Papua New Guinea Medical Journal, Vol.38, No.4, 287-294) or Varma et al 1986 (Indian Journal of Animal Sciences 56 (6): 621-627) in view of Zuk et al (U.S. Patent No. 4,281,061 issued July 28, 1981).

McManus Donald 1995 discloses a composition comprising isolated seven glycoprotein fractions ranging from GP13-Gp 50 (i.e., it includes mixture of 33, 38, 42 kD proteins of the claimed invention) that are transferred to an immunoblot (composition is on a solid phase, the enzyme electrotransfer blot test for antibody detection, see page 288, left column) for detecting antibodies from T.solium infection. The composition comprises mixture of polypeptides ranging from 10-50 kD.

Varma et al teach a composition comprising adult tapeworm antigens for identifying the adult antibodies in sera collected from human patients suffering from T.solium infection. Adult tapeworm antigens comprise a mixture of antigens for identifying antibodies in an infected individual (page 621-622, under materials and methods, Table 2 and Figure 1). However, either McManus or Varma did not disclose instructions for using in a kit and a composition in a lyophilized form.

Zuk et al teach that reagents for an immunoassay can be provided as kits as a matter of convenience and to optimize the sensitivity of the assay in the range of interest (col 22, line 62 - col 23, line 4) with instructions to use.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the reagents as taught by McManus Donald 1995 (Papua New Guinea Medical Journal, Vol.38, No.4, 287-294) or Varma in a kit format as taught by Zuk et al for the convenience and economy of the user since a variety of kits are available in the market with reagents in a lyophilized form. One would have been motivated to assemble the

reagents of the prior art in a kit format with instructions to use so that it is easy to perform the diagnostic assay in any ordinary laboratory in endemic areas that have minimum facilities.

Status of Claims

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. see MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

10/13/03

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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